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OFFICE OF PETITIONS

In re Patent No. 7,517,965

: LETTER REGARDING PATENT

Koga et al.

TERM ADJUSTMENT AND

Issue Date: April 14, 2009

: NOTICE OF INTENT TO ISSUE

Application No. 10/522,086 Filed: October 5, 2005

CERTIFICATE OF CORRECTION

Attorney Docket No. 14875-138US1/

C1-A0214P-US

This is in response to the "APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 CFR \$1.705(d)," filed June 11, 2009, requesting that the patent term adjustment determination for the above-identified patent be changed from two hundred sixty-eight (268) days to seven hundred sixteen(716) days.

The request for reconsideration of patent term adjustment is **GRANTED** to the extent indicated herein.

The patent term adjustment indicated in the patent is to be corrected by issuance of a certificate of correction showing a revised Patent Term Adjustment of **three hundred fifty-six (356) days**.

Patentees are given THIRTY (30) DAYS or ONE (1) MONTH, whichever is longer, from the mail date of this decision to respond to this decision. No extensions of time will be granted under § 1.136.

On April 14, 2009, the above-identified application matured into U.S. Patent No. 7,517,965 with a patent term adjustment of 268 days.

This request for reconsideration of patent term adjustment was timely filed within two months of the issue date of the patent. See 1.705(d).

The Office acknowledges receipt of the \$200.00 fee set forth in 37 CFR 1.18(e). No additional fees are required.

Patentees request recalculation of the patent term adjustment based on the decision in <u>Wyeth v. Dudas</u>, 580 F. Supp. 2d 138, 88 U.S.P.Q. 2d 1538 (D.D.C. 2008). Patentees assert that pursuant to <u>Wyeth</u>, a PTO delay under \$154(b)(1)(A) overlaps with a delay under \$154(b)(1)(B) only if the delays "occur on the same day." Patentees maintain that the period of adjustment due to the Three Year Delay by the Office, pursuant to 37 CFR \$1.703(b), of 448 days and the period of adjustment due to examination delay, pursuant to 37 CFR \$1.702(a), of 360 days do not overlap, as these periods do not occur on the same day.

Patentees argue that the period of adjustment due to the Three Year Delay by the Office, pursuant to 37 CFR § 1.702(b), is 448 days. Patentees correctly assert that the Three Year Delay period is triggered by the application's commencement date. The commencement date is 30 months from the priority date claimed in the international application, or earlier. The priority date claimed in the international application is July 22, 2002. Thirty months from that date is January 22, 2005, which is the beginning of the Three Year Delay period. Accordingly, the period of adjustment under § 1.702(b) is 448 days, counting the number of days beginning on January 23, 2008 and ending on April 14, 2009 when the patent issued.

Patentees assert that in addition to the three year delay period, they are entitled to a period of adjustment due to examination delay, pursuant to 37 CFR §1.702(a)(1) of 360 days for the failure by the Office to mail at least one of a notification under 35 U.S.C. 132 not later than fourteen months after the date the application fulfilled the requirements of 35 U.S.C. 371 in an international application, pursuant to § 1.702(a)(1). A restriction requirement was mailed on November 20, 2007, which was 14 months and 360 days after the § 371 fulfillment date.

Under 37 CFR § 1.703(f), Patentees are entitled to a period of patent term adjustment equal to the period of delays based on the grounds set forth in 37 CFR §1.702 reduced by the period of time equal to the period of time during which Patentees failed to engage in reasonable efforts to conclude prosecution pursuant to 37 CFR §1.704. In other words, the period of Office delay reduced by the period of applicant delay. The period of

reduction of 92 days for applicant delay is not in dispute. Patentees assert that the total period of Office delay is the sum of the period of Three Year Delay (448 days per patentees' calculation) and the period of Examination Delay (360 days, not in dispute) to the extent that these periods of delay are not overlapping.

Patentees contend there is no overlap.

As such, patentees assert entitlement to a patent term adjustment of 716 days (448 per patentees' calculation +360 reduced by 0 overlap -92 for applicant delay).

As discussed above, the Office states that the patent issued 3 years and 448 days after the application's commencement date. The Office agrees that the action detailed above was not taken within the specified time frames, and thus, the entry of period of adjustment of 360 days is correct. At issue is whether Patentees should accrue 448 (adjusted for overlap, per patentees' definition of overlap and patentees' calculation of the Three Year Delay Period) days of patent term adjustment for the Office taking in excess of three years to issue the patent, as well as, 360 days for Office failure to take a certain action within a specified time frame (or examination delay).

The Office contends that the 360 days of examination delay pursuant to 37 CFR \$1.702(a) overlap with the 488 days of delay in issuance of the patent pursuant to \$1.702(b). The Office's interpretation is consistent with patentees' alternative determination of "B Delay" set forth on Page 7/8 of the application. Patentees' first interpretation of the period of overlap has been considered and found to be incorrect. Patentees' calculation of the period of overlap is inconsistent with the Office's interpretation of this provision. 35 U.S.C. 154(b)(2)(A) limits the adjustment of patent term, as follows:

to the extent that the periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

Likewise, 37 CFR 1.703(f) provides that:

To the extent that periods of delay attributable to the grounds specified in \$1.702 overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed.

As explained in Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283 (June 21, 2004), the Office interprets 35 U.S.C. 154(b)(2)(A) as permitting either patent term adjustment under 35 U.S.C. 154(b)(1)(A)(i)-(iv), or patent term adjustment under 35 U.S.C. 154(b)(1)(B), but not as permitting patent term adjustment under both 35 U.S.C. 154(b)(1)(A)(i)-(iv) and 154(b)(1)(B). Accordingly, the Office implements the overlap provision as follows:

If an application is entitled to an adjustment under 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A). Thus, any days of delay for Office issuance of the patent more than 3 years after the filing date of the application, which overlap with the days of patent term adjustment accorded prior to the issuance of the patent will not result in any additional patent term adjustment. See 35 U.S.C. 154(b)(1)(B), 35 U.S.C. 154(b)(2)(A), and 37 CFR § 1.703(f). See Changes to Implement Patent Term Adjustment Under Twenty Year Term; Final Rule, 65 Fed. Reg. 56366 (Sept. 18, 2000). See also Revision of Patent Term Extension and Patent Term Adjustment Provisions; Final Rule, 69 Fed. Reg. 21704 (April 22, 2004), 1282 Off. Gaz. Pat. Office 100 (May 18, 2004). See also Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283 (June 21, 2004).

The current wording of § 1.703(f) was revised in response to the misinterpretation of this provision by a number of Patentees. The rule was slightly revised to more closely track the

corresponding language of 35 U.S.C. 154(b)(2)(A). The relevant portion differs only to the extent that the statute refers back to provisions of the statute whereas the rule refers back to sections of the rule. This was not a substantive change to the rule nor did it reflect a change of the Office's interpretation of 35 U.S.C. 154(b)(2)(A). As stated in the $Explanation\ of\ 37$ CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).

This interpretation is consistent with the statute. Taken together the statute and rule provide that to the extent that periods of delay attributable to grounds specified in 35 U.S.C. 154(b)(1) and in corresponding \$1.702 overlap, the period of adjustment granted shall not exceed the actual number of days the issuance of the patent was delayed. The grounds specified in these sections cover the A) guarantee of prompt Patent and Trademark Office responses, B) guarantee of no more than 3 year application pendency, and C) guarantee or adjustments for delays due to interference, secrecy orders and appeals. A section by section analysis of 35 U.S.C. 154(b)(2)(A) specifically provides that:

Section 4402 imposes limitations on restoration of term. In general, pursuant to [35 U.S.C.] 154(b)(2)(A)-(C), total adjustments granted for restorations under [35 U.S.C. 154](b)(1) are reduced as follows: (1) To the extent that there are multiple grounds for extending the term of a patent that may exist simultaneously (e.g., delay due to a secrecy order under [35 U.S.C.] 181 and administrative delay under [35 U.S.C.] 154(b)(1)(A)), the term should not be extended for each ground of delay but only for the actual number of days that the issuance of a patent was delayed; See 145 Cong. Rec. S14,718¹

The AIPA is title IV of the Intellectual Property and Communications Omnibus Reform Act of 1999 (S. 1948), which was incorporated and enacted as law as part of Pub. L. 106-113. The Conference Report for H.R. 3194, 106th Cong. 1st Sess. (1999), which resulted in Pub. L. 106-113.

As such, the period for over 3 year pendency does not overlap only to the extent that the actual dates in the period beginning three years after the commencement date overlap with the actual dates in the periods for failure of the Office to take action within specified time frames. In other words, consideration of the overlap does not begin three years after the commencement date of the application.

In this instance, the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)($\mathbf{2}$)(A) is the entire period from the application's commencement date through the date it matured into Patent No. 7,517,965, January 22, 2005 to April 14, 2009. (There were no periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)).

Therefore, 88 days, not 0 days, of patent term adjustment should have been entered for the Three Year Delay period, since the period of delay of 448 days attributable to the delay in the issuance of the patent overlaps with the adjustments of 360 days attributable to the ground specified in § 1.702(a)(1). 448 days is determined to be the actual number of days that the issuance of the patent was delayed, considering the 448 days over three years and the 360 days of examination delay. Accordingly, 88 days (448 - 360) should have been entered at issuance for a total Office day of 448 days.

As such, patentees are entitled to a patent term adjustment of 356 days (360 days examination delay + 448 days Three Year delay reduced by 360 overlap - 92 days for applicant delay).

Accordingly, the patent term adjustment indicated in the patent is to be corrected by issuance of a certificate of correction showing a revised Patent Term Adjustment of three hundred fiftysix (356) days.

The application file is being forwarded to the Certificates of Correction Branch for issuance of a certificate of correction in order to rectify this error. The Office will issue a certificate of correction indicating that the term of the above-

does not contain any discussion (other than the incorporated language) of S. 1948. A section-bysection analysis of S. 1948, however, was printed in the Congressional Record at the request of Senator Lott, See 145 Cong. Rec. S14,708-26 (1999) (daily ed. Nov. 17, 1999).

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identified patent is adjusted by three hundred fifty-six (356) days.

Telephone inquiries specific to this matter should be directed to Shirene Willis Brantley, Senior Petitions Attorney, at (571) 272-3230.

Alesia M. Brown

Senior Petitions Attorney

Office of the Deputy Commissioner

for Patent Examination Policy

ENCLOSURE: DRAFT CERTIFICATE OF CORRECTION



UNITED STATES PATENT AND TRADEMARK OFFICE **CERTIFICATE OF CORRECTION**

PATENT

: 7,517,965 B2

DATED

April 14, 2009

INVENTOR(S): Takaki Koga et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the cover page,

[*] Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 USC 154(b) by (268) days

Delete the phrase "by 268 days" and insert - by 356 days--

UNITED STATES PATENT AND TRADEMARK OFFICE

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